

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13072



2 - LABEL SAMPLE

000001

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 34926

| | | | | | |
|---------------------------|-----------------------|-------------------------------------|-------------------------|----------------------------|------------------------|
| Flag | | Flag Remarks | | | |
| Complaint Sample | | CC# EDR-2789; CFSAN Project # 13072 | | | |
| Episode Number | Origin | Basis | Sample Type | FIS Smpl Num | Status |
| | Domestic | Surveillance | Investigational | 99916035 | Completed |
| FEI | Date Collected | Product Code | Responsible Firm | PAC | Hours |
| 3002520775 | 23-NOV-98 | 54FCH09 | Manufacturer | 03F800 | 5 |
| Related Smpl Num | Position Class | Sampling District | NDC Number | Permit Number | Storage Rqrmnt. |
| | INV | ATL-DO | | | Ambient |
| Dealer is Consumer | | Crx/DEA Schedule | Recall Num | Consumer Compl. Num | Brand Name |
| Yes | | | | EDR-2789 | Calorslim |

Product Description

Product consists of dietary supplement capsules, containing 87 mg Ma Huang.

Product Label

See continuation.

Reason for Collection

Collected in response to ATL-80440; R-1135; f/u to CC# EDR-2789; CFSAN Project # 13072. Analyze for Ephedrine Alkaloids

MFG Codes

Lot 11619

Expiration Date

020100

| | | | | |
|------------------------|---|---------------------|-----------------|------------|
| Firm Legal Name | Address | Type of Firm | Firm FEI | FCE |
| Calorslim | 217 East 86th Street, Suite 312 New York, NY 10028 US | Manufacturer | 3002520775 | |

| | | | |
|--------------------|-------------------|------------------|-------------------------------------|
| Size of Lot | Est. Value | Rept Type | Date Shipped & Doc. Ref. |
| 22 capsules | \$0 | FDA484 | |

Description of Sample

Sample consists of one previously opened bottle. Bottle contains 22 capsules.

Method of Collection

Sample consists of one previously opened bottle, containing 22 capsules, collected from dealer/consumer.

How Prepared

Bottle was identified as "34926 11/23/98 EJB". Sample was placed into a brown paper bag which was officially sealed as "34926 11/23/98 Eileen J. Bannerman", with FD-525 attached.

Collector's Identification on Package and/or Label

"34926 11/23/98 EJB"

Collector's Identification on Seal

"34926 11/23/98 Eileen J. Bannerman"

| | | |
|----------------------------|---------------------------|----------------------------------|
| Sample Delivered To | Date Delivered | Orig C/R & Records To |
| Federal Express | 12/10/1998 | ATL-DO |
| | Lab w/Split Sample | Lab |
| | 0 | SEA-LAB |

| | | | |
|------------------------|----------------------|----------------------|-------------------------|
| Document Number | Document Date | Document Type | Document Remarks |
|------------------------|----------------------|----------------------|-------------------------|

Remarks

Consumer: [REDACTED]

| | | | | |
|-----------------------|-------------------------------------|----------------------|-----------------------|-------------------------|
| Payment Amount | Payment Method | 704(d) Sample | 702(b) Portion | Collector's Name |
| \$0.00 | No Charge | No | No | Eileen J Bannerman |
| Name of Signer | Date & Time of Signature | | Meaning | |
| Eileen J Bannerman | 12/09/1998 11:45 AM | | Collector | |

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Continuation:

Product Label

Product is contained in white plastic bottle labeled in part: "***CALORSLIM The Miracle Diet Aid***Dietary Supplement 30 Capsules: 380 mg each***Lot 11619 Best if used by: 020100 Manufactured for: Calorslim New York, NY 10028**".

Directions: As a dietary supplement, take 1 capsule daily

Each Capsule Contains:

| | |
|-------------------|---------|
| Pyruvic Acid | 250 mg |
| Ma Huang | 87 mg |
| Garcinia Cambogia | 17 mg |
| Gymnema Sylvestre | 17 mg |
| L-Carnitine | 10 mg |
| Chromium | 200 mcg |

Do not use if imprinted safety seal
is broken or missing.

Lot 11619

Best if used by: 020100

Manufactured for

Calorslim

New York NY 10028

CALORSLIM

The Miracle Diet Aid

Dietary Supplement

30 Capsules: 380 mg each

Warning: Do not use if you are pregnant, nursing, or have high blood pressure, heart, liver, thyroid, or psychiatric disease, diabetes, pernicious anemia, nervousness, anxiety, depression, seizure disorder, stroke, or difficulty in urination due to prostate enlargement. Consult with health care professional if you are taking a MAO inhibitor or any other prescription drug before taking this product. Discontinue use and consult your health care professional if dizziness, sleeplessness, tremors, nervousness, headache, heart palpitations or tingling sensations occur. Keep out of children's reach. Do not exceed 4 capsules in 24 hours.

FDA Disclaimer: These statements have not been evaluated by the Food and Drug Administration. This product is not intended to treat, diagnose, cure or prevent any disease.

CFSAN
Project #13072

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CALORSLIM RESEARCH PROJECT

Suite 312
217 East 86th Street
New York, NY 10028

Dear Participant:

We at Calorslim would like to take this opportunity to welcome you to the Calorslim Research Project. We feel positive that this is what you have been looking for . . . the safe and effective solution to your dieting problem. Please remember, with Calorslim all that is required is that you take 1 capsule per day. Here are some important tips that will enhance your weight loss results:

1. Eat a nutritionally balanced diet that maintains your health.
2. Make sure to drink as much water as possible.
3. Eat plenty of fresh fruits and vegetables, cooked or raw.
4. Maintain your present activity level. You do not have to start an exercise regimen.
5. It is not necessary to starve yourself. Remember, the continual maintenance of a net caloric deficiency is all that is required for absolute certainty of a positive outcome.
6. If you are overcome with a desire to eat excessively, find a substitute activity. For example, instead of rushing to the refrigerator, go for a walk, or a drive, socialize with friends, even take a nap until the urge passes.
7. Please think positively. All you have to lose with this program is W-E-I-G-H-T. Just visualize how thrilled you will be when you have achieved your weight loss goal.

Please start taking Calorslim immediately and fill out the enclosed Weight Loss Questionnaire when you are finished so that we may add your success story to all our others.

CFSAN Project #13072

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The Calorslim Research Project

Quick Weight Loss Questionnaire

Please fill out this form and mail it to: **Calorslim Research Project, Suite 312, 217 East 86th Street, New York, NY 10028**. We will add your data to our on-going research. If more than one person is using Calorslim, please copy this form and send it in together so that the other party or parties can be included in our research program.

What is your goal weight? _____

How many pounds would you like to lose? _____

What date did you begin the Calorslim Program? _____

I completed my ____ 30 Day ____ 60 Day ____ 90 Day supply on _____

This is the amount of weight I lost _____

Thank you for participating in the Calorslim Research Project. This vital information will be part of our continuing program to help battle the problem of obesity in adults. As our way of showing our thanks, we are offering all participants a special additional 20% discount off the already low Research Discount prices. Simply fill out the order form below:

CALORSLIM 20% DISCOUNT ORDER FORM

Yes, I would like to take advantage of the 20% bonus discount.
Please send

_____ bottles of the 30 Day Supply at \$ ~~19.95~~ ... \$ 15.95 each ... \$ _____
_____ bottles of the 60 Day Supply at \$ ~~29.95~~ ... \$ 23.95 each ... \$ _____
_____ bottles of the 90 Day Supply at \$ ~~38.95~~ ... \$ 30.95 each ... \$ _____

Add Shipping & Handling \$3.95
NY State Res. Add 4% Sales Tax _____

TOTAL \$ _____

I am enclosing a check ____ or money order ____
or charge my Visa ____ MC ____ Discover ____

Card # _____ Exp. Date _____

Signature _____

Name _____

Address _____

City _____ State _____ Zip _____

CFSAN Project # 13072

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CALORSLIM WEIGHT LOSS PROJECT
Suite 312
217 East 86th Street
New York, NY 10028

For Calorslim Research Project Participants

CFSAN Project #13072

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